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JUDICIARY

VETERANS' AFFAIRS, RANKING MEMBER

December 23, 2016

The Honorable Robert M. Califf, M.D. Commissioner U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

The Honorable Elliot F. Kaye Chairman U.S. Consumer Product Safety Commission 4330 East West Highway Bethesda, M.D. 20814

Dear Commissioner Califf and Chairman Kaye:

I write to urge the Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC) to address the serious safety risks associated with defective, exploding electronic cigarettes (e-cigarettes). Last week, a local ABC affiliate reported that a man from Connecticut was hospitalized after an e-cigarette exploded in his mouth, while in use. Witnesses saw the blast blow his two front teeth twenty feet in the air and knock him unconscious. Such incidents involving faulty e-cigarettes are happening with alarming regularity. As federal agencies charged with protecting consumer safety, the FDA and CPSC have an obligation to take prompt and meaningful action to protect individuals—a soaring number of which are young people, according to a recent U.S. Surgeon General report—from this danger.

E-cigarettes with faulty batteries pose not only a threat to individual safety, but to public safety—endangering all that work, live, commute, or even study in the vicinity of their users. Earlier this year, a high school sophomore in Alabama was severely burned after a classmate's ecigarette exploded and he was struck in the face by the hot battery.² According to research from the FDA, there have been 134 reports of overheating, fires and explosions of the devices in the U.S. between 2009 and January 2016.³ These incidents have resulted in house and car fires, in addition to severe personal injury.

¹ WABC-TV, "Man Speaks Out After E-Cigarette Explodes in Mouth," December 14, 2016, accessed December 21, 2016, http://abc7ny.com/news/exclusive-man-speaks-out-after-e-cig-explodes-in-mouth/1656673/.

² CNN, "E-cigarette explodes, burns high school student." May 10, 2016, accessed December 21, 2016, http://www.cnn.com/videos/us/2016/05/10/e-cigarette-explodes-in-classmates-face-pkg.waff/video/playlists/e-cigarettes/.

³ Sara Randazzo, "E-Cigarette Users Sue Over Exploding Devices," *Wall Street Journal*, July 3, 2016, accessed December 21, 2016, http://www.wsj.com/articles/e-cigarette-users-sue-over-exploding-devices-1467538202

As Ranking Member of the Senate Subcommittee on Consumer Protection, Product Safety, Insurance, and Data Security, I have noted that there have been a number of past recalls involving lithium-ion batteries and in a wide range of consumer products—ranging from flashlights and hoverboards, to laptops. Despite frequent accounts in the media of exploding ecigarettes, there has yet to be a single recall by any e-cigarette manufacturer. I am troubled by this lack of action to date, and also concerned that the e-cigarette industry is cutting corners and not taking appropriate steps to ensure the electrical safety of the products they are manufacturing and marketing.

Unlike other electronic devices, there is no consensus standard—national or otherwise—for testing and ensuring the safety of the lithium-ion batteries in e-cigarettes. The Institute of Electrical and Electronics Engineers (IEEE), a standards-setting body, has developed product-specific design standards for the rechargeable batteries in cellular phones and laptops. Both of these standards were developed through a consensus process and required the commitment and dedication of diverse parts of the respective industries to prioritizing customer safety. In contrast, the e-cigarette industry has failed to even initiate a process to create a standard for rechargeable batteries in e-cigarettes, suggesting they are much more interested in profits than prioritizing consumer safety. Even worse, it is unclear if e-cigarette manufacturers are even in compliance with any general lithium-ion battery standards, such as the ones created by UL. 5

Furthermore, as noted by the U.S. Fire Administration in a 2014 report, e-cigarettes "are different from other electronic consumer devices" as they have a unique cylindrical nature and are "more likely than other products with lithium-ion batters to behave like 'flaming rockets' when a battery fails." These realities about e-cigarette product design make it ever more pertinent that the industry ensure compliance with any safety standards and create standards to guarantee consumer safety. Cell phones and laptops have product-specific safety standards for their batteries, and given the high rate of incidents involving e-cigarette batteries, so too should e-cigarettes.

Accordingly, I urge the FDA and CPSC to take action to protect consumers from the significant safety hazards posed by e-cigarettes. First, all e-cigarette models that have exploded should be immediately recalled. Such dangerous products must also be removed from store shelves, online marketplaces, and out of the mouths and pockets of consumers. Second, I urge you to work with the e-cigarette industry to create a consumer safety focused standard for the rechargeable batteries in e-cigarettes and ensure the industry's compliance with any applicable existing battery standards. Third, I respectfully request FDA and CPSC to transmit to my office all incident reports (filed either through FDA's Safety Reporting Portal or CPSC's National Electronic Injury Surveillance System) involving explosions of e-cigarettes, from January 2009 to December 2016. This information is critical to understanding the magnitude and scope of this

⁴ IEEE Standards Association, "IEEE-SA Mobile Battery Standards," accessed December 21, 2016, https://standards.ieee.org/develop/corpchan/mobilebat.pdf.

⁵ Tom O'Hara, "Navigating the Regulatory Maze of Lithium Battery Safety," *Battery Power*, November 2013, accessed December 21, 2016, http://www.batterypoweronline.com/main/wp-content/uploads/2013/11/Intertek_Regulatory-Maze-WP.pdf.

⁶ U.S. Fire Administration, "Electronic Cigarette Fires and Explosions," October 2014, 5, accessed December 21, 2016, https://www.usfa.fema.gov/downloads/pdf/publications/electronic_cigarettes.pdf.

issue, and will help guide our follow-up efforts. Finally, I urge your two agencies to work together, leveraging your respective expertise, to effectively address the peril of exploding ecigarettes.

Thank you for attention to this important matter. I respectfully request a response no later than January 20, 2017.

Sincerely,

Richard Blumenthal

United States Senate